

SAFETY DATA SHEET

Date: 02/14/20

Generic Name: Naproxen Sodium Tablets, USP 275 mg & 550mg

 Brand Equivalent: Anaprox[®] DS (naproxen sodium) Tablets

SECTION 1: IDENTIFICATION	
Product Name	Naproxen Sodium Tablets, USP 275 mg & 550mg
Active substance	Naproxen Sodium
Synonyms	N/A
Formula	C ₁₄ H ₁₃ NaO ₃
Intended Use	Anti-inflammatory, Analgesic
Chemical Name	(S)-6-methoxy- α -methyl-2-naphthaleneacetic acid, sodium salt
How Supplied	275 mg: White, capsule shaped, film coated tablets, debossed with '432' on one side and 'SG' on other side. 550 mg: White, capsule shaped, film coated tablets, debossed with '433' on one side and 'SG' along with break line on other side.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723
2. HAZARDS IDENTIFICATION	
Not considered hazardous when handled under normal conditions.	
EMERGENCY OVERVIEW	
Caution	Product poses little or no hazard if spilled and no unusual hazard if involved in a fire.
Human effects and Symptoms of Overexposure	
Acute Effects of Exposure: Exceeding the recommended dosage may cause: nausea, vomiting, ringing in the ears or a loss of hearing occurs. Drowsiness, confusion, irregular heartbeat, headache, high blood pressure.	
Chronic Effects of Exposure: Chronic over exposure to this product may cause effects as noted under acute over exposure.	
Routes of Entry	Oral
Carcinogenicity	
NTP:	None
IARC:	None
OSHA:	None
Medical Conditions	Blood disorders, digestive disorders, kidney disorders, high blood pressure, do not take this product without first consulting a health

	professional, if you have any of the following conditions; pregnant or nursing a baby, stomach problems that last or come back frequently, gastrointestinal ulcers, bleeding problems, taking prescription medications, taking any other drug containing an NSAID (Prescription r nonprescription), taking a blood thinning (anticoagulant) or steroid drug.
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3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Naproxen Sodium, USP	26159-34-2	71.48%
Microcrystalline Cellulose, NF (Avicel PH 102)	9004346	*
Povidone, USP (Plasdone K 29/32)	9003398	*
Talc, USP (140)	14807966	*
Magnesium Stearate, NF	557040	*
SheffCoat White 04	Mixture	*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
Eye contact	Immediately flush with plenty of water for at least 15 minutes. Get medical attention.
Skin contact	Not applicable
Inhalation	Not applicable
Ingestion	In case of overdose, contact your regional poison control centre or physician immediately.
First aid other	<p>Stop use and ask a doctor if you feel faint, vomit blood, or have bloody or black stools, pain gets worse or lasts more than 10 days, have difficulty swallowing, develop heartburn, redness or swelling is present; new symptoms occur; Allergy Alert: Naproxen Sodium may cause a severe allergic reaction, especially in people allergic to Aspirin. Symptoms may include: hives, facial swelling, asthma (Wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding Warning: This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause stomach bleeding. The chance is higher if you are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing an NSAID (aspirin, ibuprofen, naproxen or others), have 3 or more alcoholic drinks every day while using this product, take more or for long time than directed.</p>

5. FIRE-FIGHTING MEASURES	
Flash Point	Not applicable
Flammable Limits	
Upper explosion Limit (UEL %)	Not established
Lower explosion Limit (UEL %)	Not established
Auto-ignition Temperature	Not applicable
Suitable extinguishing media	All extinguishing media are suitable
Special Fire Fighting Procedures	Fire fighters should be equipped with Self-Contained breathing apparatus to protect against potentially toxic and irritating fumes

6. ACCIDENTAL RELEASE MEASURES	
Spill or Leak Procedures	Spill should be swept up and placed in appropriate containers for disposal. Avoid creating dusty conditions

7. HANDLING AND STORAGE	
Handling /Storage Precautions	Keep this and all drugs out of the reach of children. Avoid contact with eyes. Avoid excessive contact with skin or clothing. Wash thoroughly after handling. Use normal precautions for storage of a drug.
Storage Temperature	Room Temperature
Shelf life	Do not use after expiration
Special Sensitivity	None known
Specific use(s)	Human pharmaceutical use

8. Exposure controls/Personal protection	
Protective Measures	Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.
Respiratory Protection	Under normal handling of use, respiratory protection is not required
Eye protection	None for normal use
Ventilation Requirements	Under normal handling of use, special ventilation is not required
Skin and body Protection	No special skin protection requirements during normal handling and use
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i>	Tablets
Physical State	
Color	White
Form	Coated Tablets
Odor	Not available
Odor Threshold	Not available
pH	Not available
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Non-hygroscopic
Log Octanol/Water Partition Coeff [log Kow]	3.18
Surface Tension	Not available
pKa	4.15
Particle Size	Not available
Solubility, Water	Not soluble
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	155 °C
Oxidizing Potential	Not available
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
Stability	Stable
Hazardous Polymerization	Will not occur
Substances to Avoid	See carton for full directions and warnings
Conditions to Avoid	Avoid extreme heat, avoid contact with moisture and water
Decomposition products	None known

11. Toxicological Information	
Toxicity Note	No data available

12. Ecological Information	
Ecological Note	No data available.

13. Disposal considerations	
Waste Disposal	Dispose of waste must be in accordance with all applicable Federal, State and local laws.

14. Transport Information	
DOT	Not Regulated
IMDG	Not Regulated
ICAO/IATA	Not Regulated
IMO	Not Regulated

15. Regulatory Information	
United States Federal Regulations OSHA Hazcom Standard Rating	Not subject to OSHA
SARA Section 302 Extremely Hazardous Substance	Components/ CAS Number Exempt
SARA Section 311/312 Hazard Categories	Exempt from SARA Section 311/312
SARA Section 313 Toxic Chemicals	Components/ CAS Number Exempt
TSCA Inventory List	This product is exempt from TSCA under section 3(2) (B) (Vi) when used for pharmaceutical application
RCRA Status	If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under

	RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste
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16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	<i>02/14/2020</i>
Revision	00
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